



PATENT
ATTORNEY DOCKET NO. 01997/521002

Certificate of Mailing: Date of Deposit: March 25, 2004

I hereby certify under 37 C.F.R. § 1.8(a) that this correspondence is being deposited with the United States Postal Service as **first class mail** with sufficient postage on the date indicated above and is addressed to: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Christine M. Colbert

Printed name of person mailing correspondence

Signature of person mailing correspondence

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Rajesh Ranganathan et al.	Art Unit:	1632
Serial No.:	09/559,622	Examiner:	Joseph T. Woitach
Filed:	April 27, 2000	Customer No.:	21559
Title:	NOVEL SEROTONIN-GATED ANION CHANNEL		

Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRELIMINARY REMARKS

In connection with the concurrently filed Request for Continued Examination of the above-captioned application, and prior to examination, Applicants submit the following preliminary remarks in response to the issues raised in the Advisory Action mailed on November 19, 2003.

In the Advisory Action, the Examiner stated:

The present claims provide no structural limitation (no[r] do the proposed claims) which differentiates it from the fact pattern examined in Ex parte Maizel. The ability of a polynucleotide to hybridize is a functional limitation for isolating a given polypeptide. Even if one were to find evidence that particular hybridization conditions result in polynucleotides of a given percent identity, the specification fails to teach or describe what particular sequences among all those that would hybridize that meet any functional limitation of being functional/usable in any given assay.

As an initial matter, Applicants note that the claims, as amended in the Supplemental Amendment filed on September 9, 2003, recite highly stringent hybridization conditions (see, e.g., page 34, lines 2-6, of the specification). The highly stringent hybridization conditions provide a structural limitation for the nucleic acid sequences recited in the present claims, as is evidenced by the fact pattern set forth in Example 9 of the U.S. Patent & Trademark Office's Written Description Guidelines ("the Guidelines").

In Example 9, the specification discloses a single cDNA species which encodes a protein that binds to a dopamine receptor and stimulates adenylate cyclase. The claim in this example is directed to a genus of nucleic acids, which must hybridize under high stringency conditions with the disclosed cDNA and must encode a protein with a specific activity. In concluding that the written description requirement was satisfied in this Example, the Guidelines state:

[A] person of skill in the art would not expect substantial variation among species encompassed within the scope of the

claims because the highly stringent hybridization conditions set forth in the claim yield structurally similar DNAs. Thus, a representative number of species is disclosed, since highly stringent hybridization conditions in combination with the coding function of DNA and the level of skill and knowledge in the art are adequate to determine that applicant was in possession of the claimed invention. (Emphasis added.)

The facts of the present case are clearly analogous to those presented in Example

9. Applicants' claims encompass a nucleic acid molecule that specifically hybridizes under highly stringent conditions to the complement of the sequence set forth in SEQ ID NO:2, wherein the nucleic acid molecule encodes a serotonin-gated anion channel that selectively permits passage of anions into or out of the cell, or across a membrane, in response to binding serotonin. As in Example 9, Applicants' specification describes (i) at least a single species of a nucleic acid molecule falling within the scope of the claimed genus and (ii) an activity (serotonin-gated anion channel function) of the protein encoded by the nucleic acid molecule. A person of ordinary skill in the art would not expect substantial variation among species encompassed within the scope of the invention as claimed. As is noted in the Guidelines, the stringent hybridization requirement necessarily yields structurally similar nucleic acids. This structural similarity, when combined with the functionality requirement, describes a genus of nucleic acid molecules. Therefore, in this case, as in Example 9, the single disclosed species is representative of the genus.

In addition, in view of the structural limitation present in Applicants' claims, the

present case is clearly differentiated from the fact pattern of *Ex parte Maizel*, 27 U.S.P.Q.2d 1662 (Board of Appeals and Interferences, 1992). The claim under consideration in *Ex parte Maizel* recited the phrase “or a biologically functional equivalent thereof,” but provided no structural limitations for this functional equivalent. In contrast, as is noted above, the present claims require that the nucleic acid sequence that encodes a serotonin-gated anion channel hybridizes under highly stringent conditions to the complement of the sequence of SEQ ID NO:2 (a structural limitation) and that the serotonin-gated anion channel selectively permits passage of anions into or out of a cell, or across a membrane, in response to serotonin. Thus, unlike the claim in *Ex parte Maizel*, the present claims include both functional and structural limitations, and the current case therefore is not analogous to the cited case.

In view of the arguments set forth above, Applicants submit that the written description rejection of the present claims, as amended in the Supplemental Amendment filed on September 9, 2003, should be withdrawn.

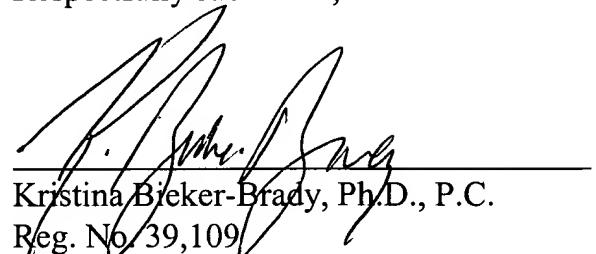
CONCLUSION

Applicants submit that the application is in condition for allowance and this action is hereby respectfully requested.

If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: March 15, 2004


Kristina Breker-Brady, Ph.D., P.C.
Reg. No. 39,109

Clark & Elbing LLP
101 Federal Street
Boston, MA 02110
Telephone: 617-428-0200
Facsimile: 617-428-7045